

ABSTRACT OF THE DISCLOSURE

Disclosed and claimed are methods of non-invasive genetic immunization in an animal and/or methods of inducing a systemic immune or therapeutic response in an animal following topical application of vectors, products therefrom and uses for the methods and products therefrom. The methods can include contacting skin of the animal with a vector in an amount effective to induce the systemic immune or therapeutic response in the animal. The vector can include and express an exogenous nucleic acid molecule encoding an epitope or gene product of interest. The systemic immune response can be to or from the epitope or gene product. The nucleic acid molecule can encode an epitope of interest and/or an antigen of interest and/or a nucleic acid molecule that stimulates and/or modulates an immunological response and/or stimulates and/or modulates expression, e.g., transcription and/or translation, such as transcription and/or translation of an endogenous and/or exogenous nucleic acid molecule; e.g., one or more of influenza hemagglutinin, influenza nuclear protein, influenza M2, tetanus toxin C-fragment, anthrax protective antigen, anthrax lethal factor, rabies glycoprotein, HBV surface antigen, HIV gp 120, HIV gp 160, human carcinoembryonic antigen, malaria CSP, malaria SSP, malaria MSP, malaria pfg, and mycobacterium tuberculosis HSP; and/or a therapeutic, an immunomodulatory gene, such as co-stimulatory gene and/or a cytokine gene. The immune response can be induced by the vector expressing the nucleic acid molecule in the animal's cells. The animal's cells can be epidermal cells. The immune response can be against a pathogen or a neoplasm. A prophylactic vaccine or a therapeutic vaccine or an immunological composition can include the vector. The animal can be a vertebrate, e.g., a mammal, such as human, a cow, a horse, a dog, a cat, a goat, a sheep or a pig; or fowl such as turkey, chicken or duck. The vector can be one or more of a viral vector, including viral coat, e.g., with some or all viral genes deleted therefrom, bacterial, protozoan, transposon, retrotransposon, and DNA vector, e.g., a recombinant vector; for instance, an adenovirus, such as an adenovirus defective in its E1 and/or E3 and/or E4 region(s). The method can encompass the vector being chosen from the group consisting of gram negative and gram positive bacteria. The vector can be gram negative bacteria, preferably *Salmonella* and most preferably *Salmonella typhimurium*. The method can encompass applying a delivery device including the vector to the skin of the animal, as well as such a method further including disposing the vector in and/or on the delivery device. The vector can have all viral genes deleted therefrom. The vector can induce a therapeutic and/or an anti-tumor effect in the animal, e.g., by expressing an oncogene, a tumor-suppressor gene, or a tumor-associated gene. Immunological products generated by the expression, e.g., antibodies, cells from the methods, and the expression products, are likewise useful in *in vitro* and *ex vivo* applications, and such immunological and expression products and cells and applications are disclosed and claimed.